



Q2 2023 Financial Results Conference Call

August 9, 2023
Nasdaq: BLTE

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Belite Participants



Management



Tom Lin, MMED, PhD, MBA
(Chairman, CEO)

- 10+ years of executive management role in biotech, including 2 IPO
- Over 10 new drug developments in multiple therapeutic areas, including Ophthalmology, CNS, Cardiovascular, Oncology, Immuno-Oncology, Immunotherapies, Immunosuppressants
- University of Sydney, University of Melbourne, Harvard Medical School, Columbia University, London Business School, HK University



Nathan Mata, PhD
(CSO)

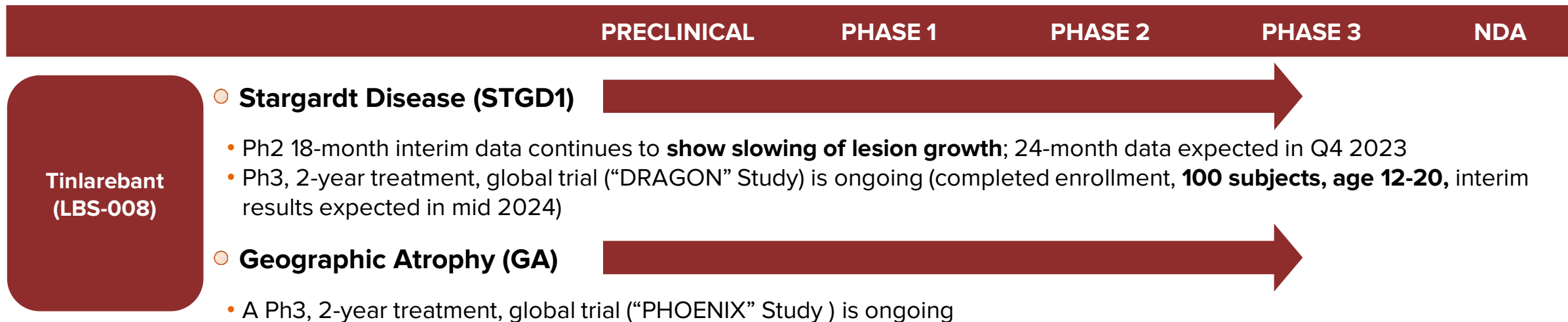
- 15+ years of ophthalmic drug development experience across numerous indications including 2 NDAs for topical therapeutics (Durezol® and Zirgan®)
- Led the clinical development efforts for first RBP antagonist in advanced dry AMD and first visual cycle modulator in advanced dry AMD and STGD1
- Introduced the industry's first STGD1 ABCA4 knockout mice model
- University of Texas



H.Y. Chuang, CFA, MBA, FRM
(CFO)

- 13+ years of capital market experience, closed more than US\$32 billion transactions
- Wanda, Suning, CITIC Securities
- Columbia University, London Business School, HK University

Belite Bio Overview



- **Tinarebant** is a **novel once daily oral tablet** designed to bind to serum **retinol binding protein 4 (RBP4)** as a means to specifically reduce retinol delivery to the eye. This approach is intended to **slow or halt the formation of the toxic retinol-derived by-products** which are generated in the visual cycle and are **implicated in progression of STGD1 and GA**
- Belite Bio believes that **early intervention directed at emerging retinal pathology**, which is not mediated by inflammation, would be the best approach to potentially slow disease progression in STGD1 & GA
- **Unmet Market Opportunity:**
 - No FDA approved treatments for STGD1
 - No FDA approved orally administered treatments for GA
- **Fast Track Designation & Rare Pediatric Disease** in US and **Orphan Drug Disease** designation in US / EU for STGD1
- In-licensed **9 active patent families**. Composition of matter patent until at least **2035** without patent term extension



STGD1 Clinical Trials

Clinical Trial Design Overview in STGD1

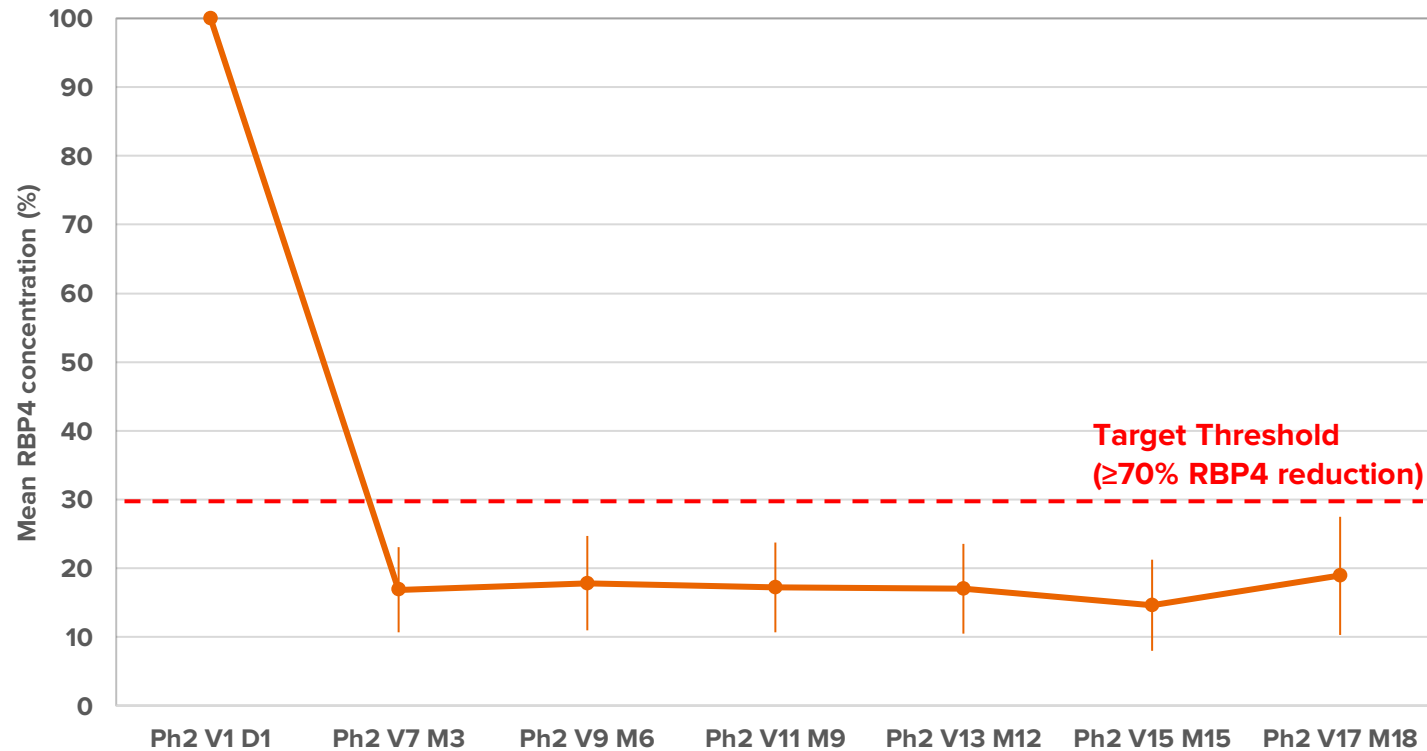


Reduction in Lesion Growth Rate (DDAF) as Measured by Retinal Imaging is the FDA Accepted Primary Endpoint in STGD1 and GA

| | STGD1 Phase 2 “LBS-008-CT02” <i>(Preliminary 18-Month Interim Data Available)</i> | STGD1 “Dragon” Phase 3* <i>(Enrolling)</i> |
|-------------------------------|---|--|
| Enrollment | 13 subjects (QDAF, no DDAF) | At least 90 subjects targeted (must have DDAF) |
| Sites | Australia & Taiwan | Global |
| Masking | Open Label | Double Blind |
| Placebo | N/A | 2:1 ratio (Tinlarebant : Placebo) |
| Treatment duration | 2 years | 2 years |
| Primary measures | Safety & tolerability, optimal dose | Efficacy as measured through DDAF lesion growth rate, safety & tolerability |
| Other measures | DDAF, QDAF, BCVA, SD-OCT, microperimetry | QDAF, BCVA, SD-OCT, microperimetry |
| Interim analysis | Yes | Yes |
| Key inclusion criteria | 12-18 years old, diagnosed STGD1 with at least one mutation identified in the ABCA4 gene | 12-20 years old, diagnosed STGD1 with at least 1 mutation identified in the ABCA4 gene, atrophic lesion size within 3 disc areas (7.62 mm ²), a BCVA of 20/200 or better |

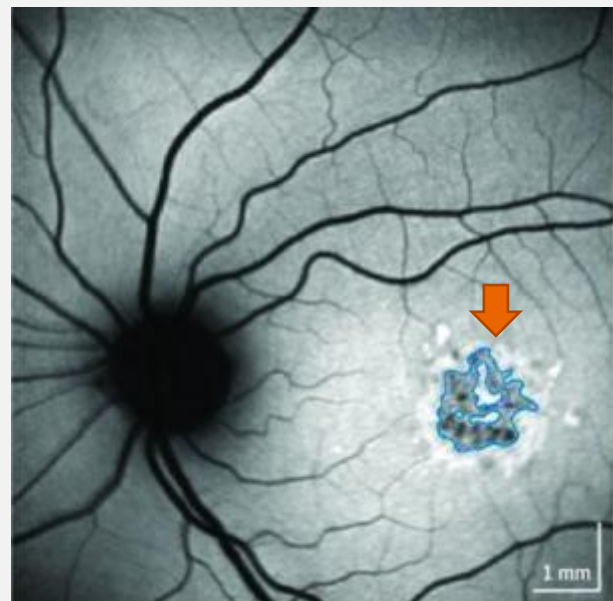
*FDA may require another clinical trial depending on the data from the ongoing Phase 3 study

Ph2 18-month: Reduction of Plasma RBP4 Levels



- Plasma RBP4 was reduced by approximately **80%** relative to baseline during daily dosing at **5 mg** over 18 months

Ph2 18-month: Change in combined lesion size

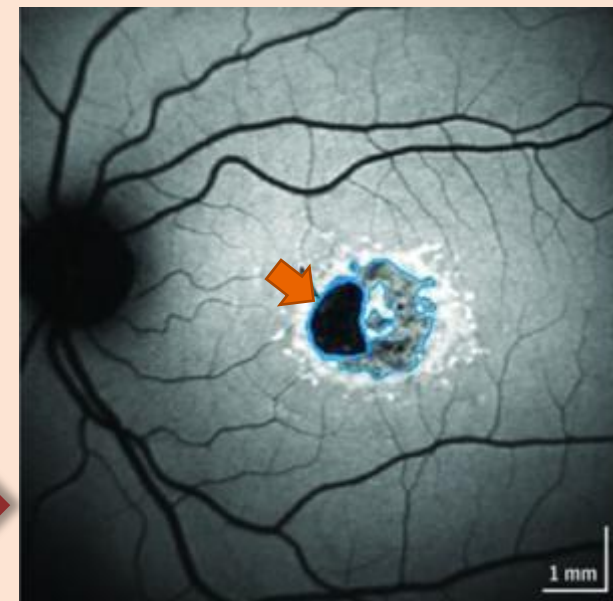


QDAF lesion (boundary outlined in blue) in STGD1 patient as measured by fundus autofluorescence (FAF) imaging.

QDAF lesions may be amenable to rescue.

DDAF lesion (“dead retina”) in STGD1 patient as measured by FAF imaging.

DDAF lesions indicate irreversible loss of photoreceptor cells.



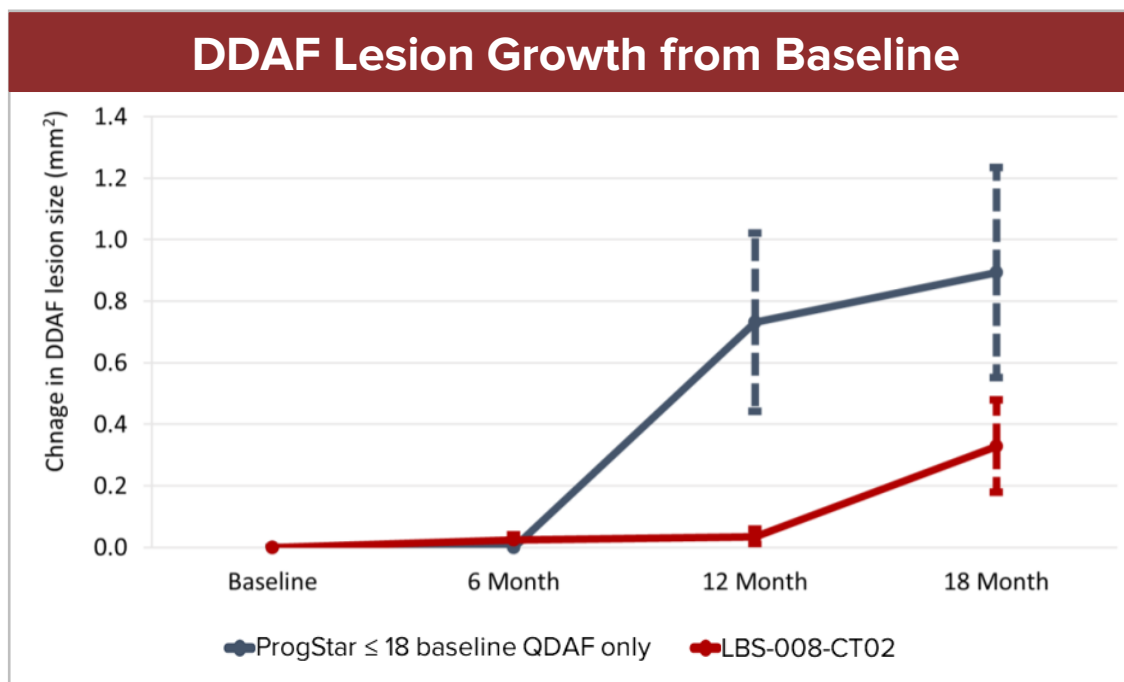
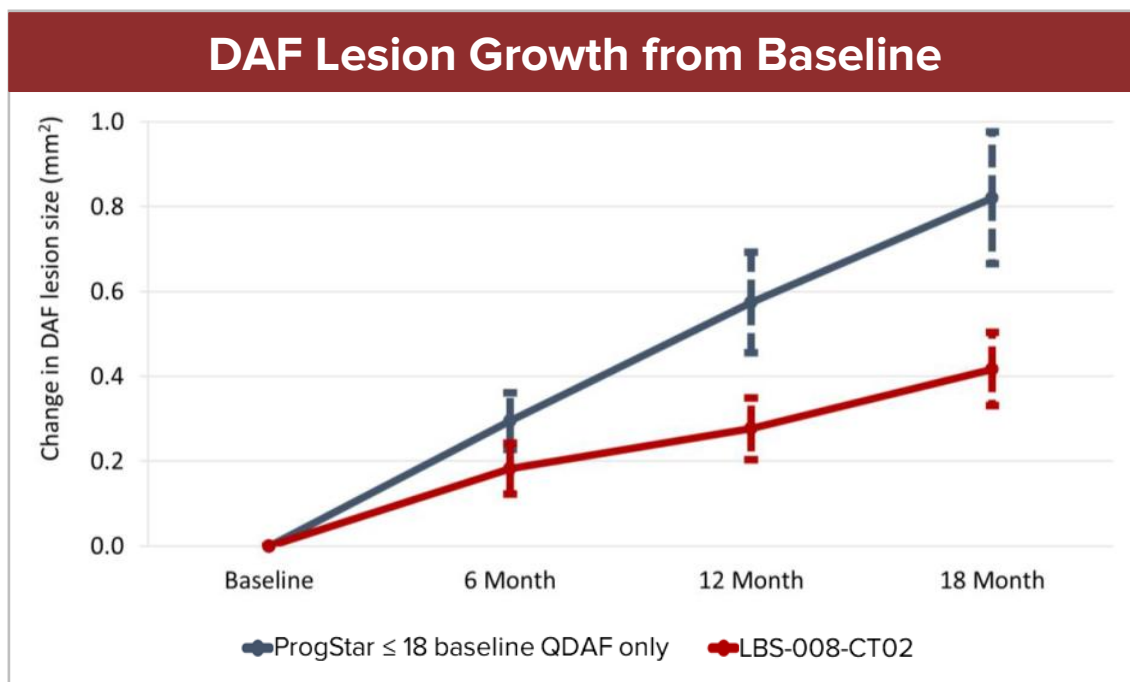
- The combined QDAF and DDAF lesion area is termed decreased autofluorescence (DAF)
- Comparison of mean DAF lesion growth rates between Georgiou et al. (2020) and subjects in LBS-008-CT02 revealed a 60% reduction among subjects in LBS-008-CT02

| Data Source | Mean DAF lesion growth rate (DAF = DDAF+QDAF) |
|--|---|
| The Prospective Cohort Study of Childhood-Onset STGD1 by Georgiou et al. 2020 ⁽¹⁾ | 0.69 ± 0.72 mm ² /year, n=53 |
| Belite Bio 18-month data | 0.28 ± 0.28 mm²/year, n=12 |

Ph2 18-month: Lesion growth rates versus ProgStar

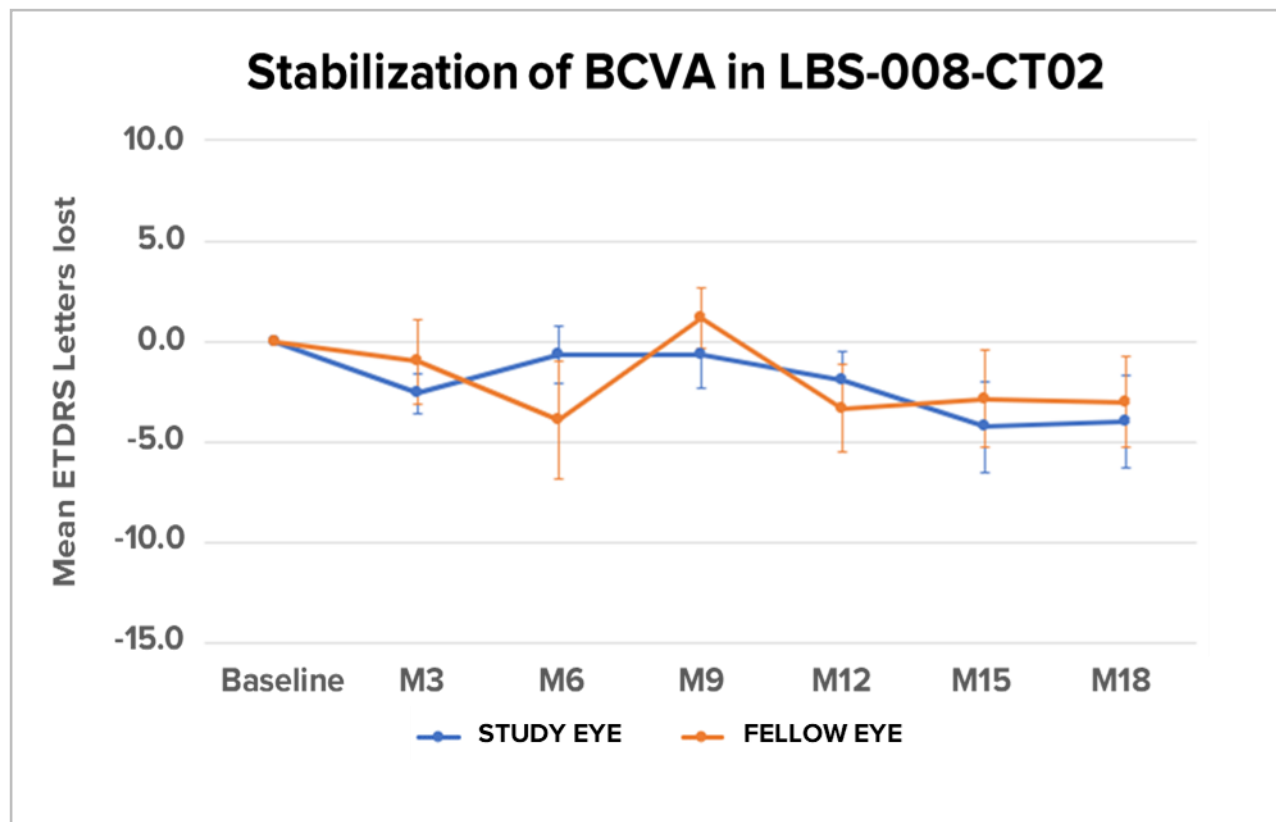


- A comparison of DAF and DDAF lesion growth among ProgStar subjects with similar baseline characteristics as subjects in LBS-008-CT02 (i.e., ≤ 18 years old with no DDAF at baseline) was performed



- No development of DDAF** in 7 of 12 subjects (58.3%) at the 18-month timepoint
- Comparing to ProgStar subjects ≤ 18 years old with no DDAF at baseline, LBS-008-CT02 subjects showed reduced expansion of both DAF and DDAF lesions from baseline

Ph2 18-month: Visual Acuity Data



- **A trend for maintaining BCVA** in a majority of subjects was observed following 18 months of treatment
- Mean change in BCVA (ETDRS letters lost) within the study cohort over 18 months of treatment was **-3 ± 1** letters in the Study eye and **-2 ± 2** letters in the Fellow eye

Ph2 18-month: Well-Tolerated Drug-Related Adverse Events



| Adverse Events | Severity | Frequency (#patients) | % Recovered |
|-------------------------|----------|-----------------------|-------------|
| Xanthopsia/Chromatopsia | Mild | 9/12 (75%) | 6/9 (66.7%) |
| Delayed Dark Adaptation | Mild | 9/12 (75%) | 1/9 (11.1%) |
| Night Vision Impairment | Mild | 1/12 (8.3%) | 0 |

- Tinlarebant (5 mg p.o., daily) continues to be **safe** and **well tolerated** in adolescent STGD1 patients
- Tinlarebant treatment produced a mean **80% reduction of RBP4** (from baseline) throughout the study
- Delayed Dark Adaptation and Xanthopsia/Chromatopsia are the most common drug related ophthalmic AEs
- All instances of Delayed Dark Adaptation, Night Vision Impairment, and Xanthopsia/Chromatopsia were **mild** and **transient**
- No severe and moderate drug related AEs reported and no AEs requiring discontinuation of treatment
- No clinically significant findings in relation to vital signs, physical exams, cardiac health, or organ functions



Fenretinide Proof-of-Concept Study

Reduction of RBP4 Slows Lesion Growth in GA Subjects



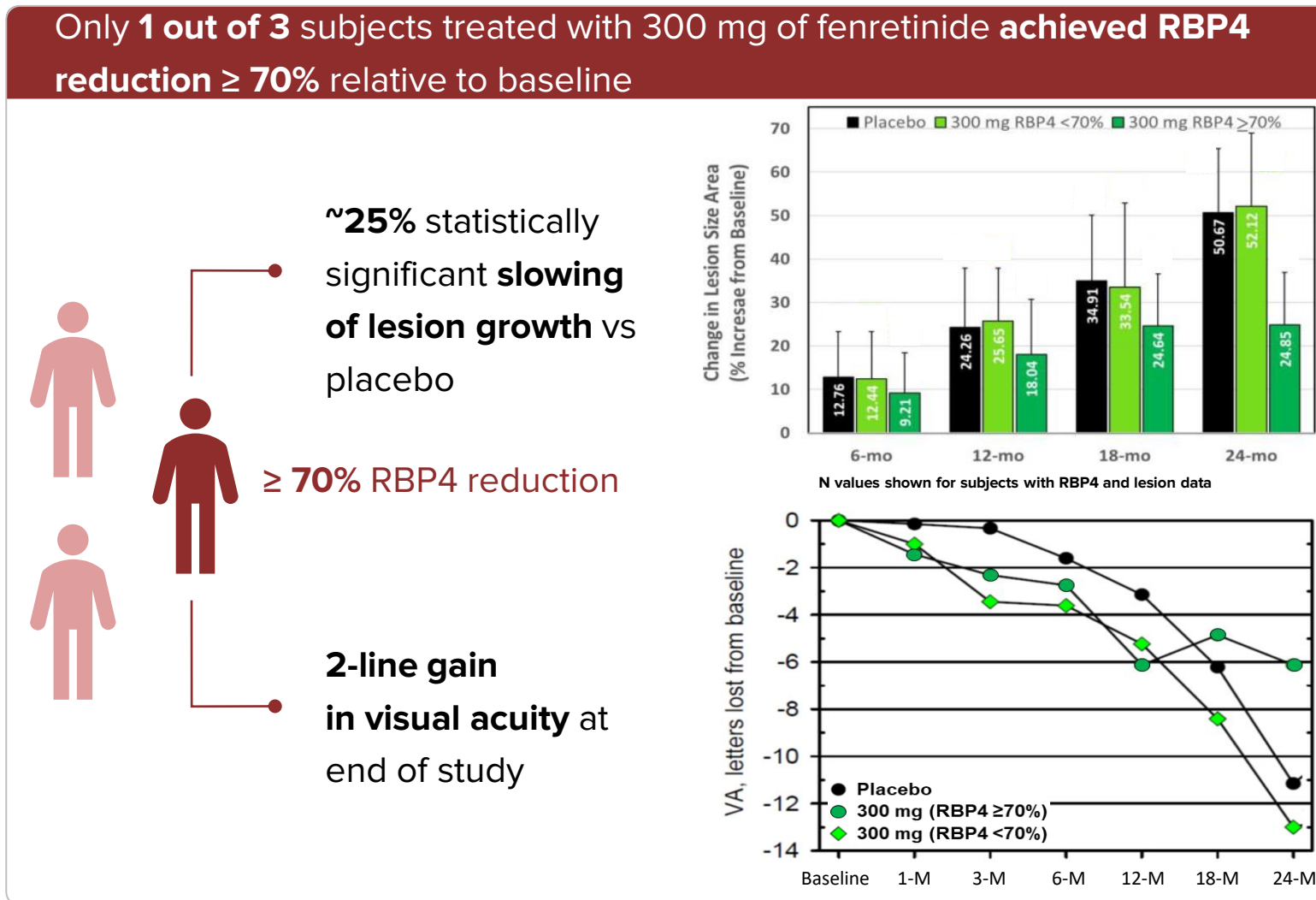
Sirion's Ph 2 Proof-of-Concept Fenretinide Study in GA Reinforces Tinalarebant Potential

Fenretinide is a synthetic retinoid with **broad retinoid pathway capabilities**

- Developed as an anti-cancer drug
- Competing with retinol for RBP4 binding is a side effect

Tinalarebant is designed to overcome the lower potency and limited bioavailability of fenretinide

| Agent | Ki RBP4 |
|--------------|---------|
| Tinalarebant | 2 nM |
| Fenretinide | 200 nM |



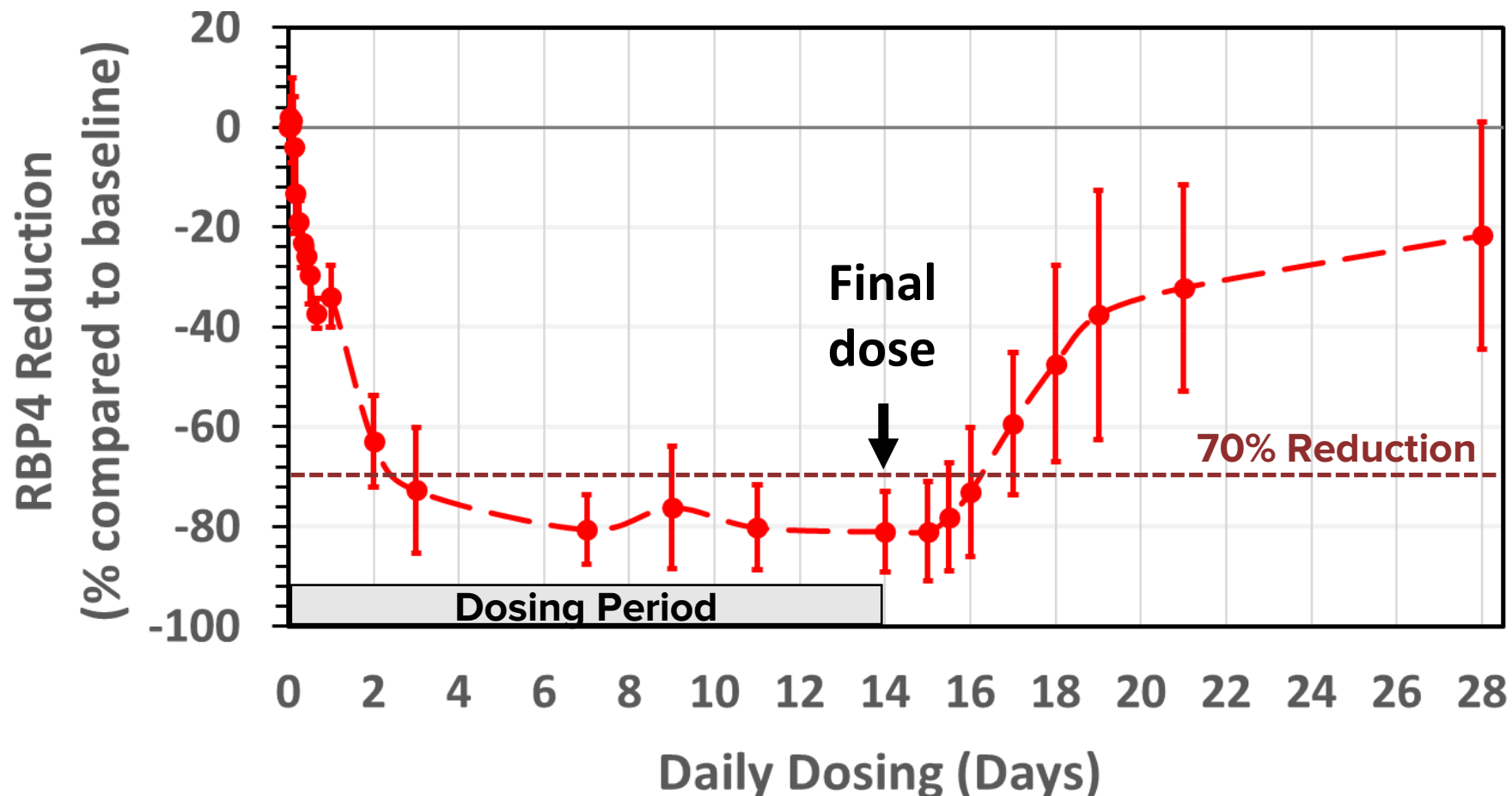


Phase 3 Geographic Atrophy

Tinlarebant: $\geq 70\%$ Reduction of RBP4



Phase 1, 5mg Daily Dosing in Healthy Adults: Mean Percent Reduction of RBP4 (excludes placebo)



Clinical Trial Design Overview in GA



- **Established Efficacy Endpoint** – Reduction in Lesion Growth Rate (DDAF) as Measured by Retinal Imaging is the FDA Accepted Primary Endpoint for STGD1 and GA
- **Early Intervention** – Targeting patients with small lesion size to potentially slow disease progress at an early stage
- **Oral Once a Day Treatment** – well suited for long term treatment for chronic diseases
- **Broad Potential** – Primary focus on GA; potential to treat earlier stages (e.g., intermediate AMD)

| | GA Phase 3 “Phoenix”* |
|---------------------------|--|
| Enrollment | Approximately 430 subjects targeted (Expected to begin enrolling in mid-2023) |
| Sites | Global |
| Masking | Double Blind |
| Placebo | 2:1 ratio (Tinlarebant : Placebo) |
| Treatment duration | 2 years |
| Primary measures | Efficacy as measured through DDAF lesion growth rate, safety & tolerability |
| Other measures | QDAF, BCVA, SD-OCT, microperimetry |
| Interim analysis | Yes |

*Additional Phase 3 study expected to be required prior to NDA filing



Q2 2023 Financial Results

For more info please visit: www.belitebio.com

Q2 2023 Financial Results



| (In thousands of USD) | For the Three Months Ended June 30 | |
|---------------------------------|------------------------------------|---------|
| | 2022 | 2023 |
| Total operating expenses | 2,506 | 6,871 |
| - R&D | 1,579 | 5,516 |
| - G&A | 927 | 1,355 |
| Net loss | (2,391) | (6,811) |

- Cash: \$57.4 million



Key Milestones

For more info please visit: www.belitebio.com


Key Milestones




Q1, 23

- Initiated Phase 3 PHOENIX study in GA 

Q2, 23

- April 25 - ARVO Presentation of 18-month data from Phase 2 study in STGD1 

H2, 23

- Completed the enrollment of Phase 3 DRAGON study in STGD1 
- Topline 24-month data from Phase 2 study in STGD1 expected

H1, 24

- Interim results from Phase 3 DRAGON study in STGD1 expected



QA